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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/308,237 05/21/99 OHKI

H 0018-1052-0P

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EXAMINER

BORIN, M

ART UNIT	PAPER NUMBER
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1631

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DATE MAILED:

12/19/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/308,237

Applicant(s)

OHKI ET AL.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 1999.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 2-10, 14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

Status of Claims

Claim 15 is added. Claims 1-15 are pending.

Response to restriction requirement filed 12/22/99 is acknowledged. Applicant elected, with traverse, Group I, claims 1-9,11,13. New claim 15 is also in Group I. Applicant argues that there is a special technical feature between Groups I-III. The restriction requirement, however, explained why the linking technical feature is not considered to be a "special technical feature" required for the unity of invention. The restriction requirement is still deemed proper and is therefore made FINAL. Claims 10,12,14 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected groups. In regard to Groups II, III, as was stated in the restriction requirement, if a product claim is found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

As per election of species, the election made is not quite clear. Applicant informs that the elected species is "4-[5-(4-pentyloxyphenyl)isoxazol-3-yl] where R1 is benzoyl and R2 is hydroxyl". This is understood as election of 4-[5-(4-pentyloxyphenyl)isoxazol-3-yl]benzoyl (last species in the list of R1 values in claim 1). Claims reading on the elected species are claims 1 and 11. Claims 2-9,15 are withdrawn from consideration as drawn to non-elected species.

Insofar as the elected species recited in claim 1 has been found to be neither anticipated nor rendered obvious by prior art, the search of the Markush - type claim 1 was extended.

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Information Disclosure Statement

Applicants' Information Disclosure Statements filed 8/3/99 and 3/22/00 have been received and entered into the application.

Abstract

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b).
An abstract on a separate sheet is required.

Sequence Listing

The Sequence Listing was approved by STIC for matters of form.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,11 are rejected under 35 U.S.C. 112, second paragraph, for failing to particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant . Claim 1 has multiple instances of language of the type "aroyl substituted with heterocyclic group which has...[substituent] ... which may have [other substituents]". It is not clear whether the substituent is connected to "aroyl" or to "heterocycle". Further, the site of attachment of the next level of substituents (indicated as [other substituent]) is also not clear. Accordingly, the

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structure of the compounds as claimed is vague and indefinite and one of ordinary skills in the art would not be reasonably appraised of the scope of the invention.

It is noted that claim 15 (currently withdrawn from consideration) lacks antecedent basis as it is drawn to compounds wherein R1 is unsubstituted benzoyl, whereas in generic claim 1 R1 is always substituted aroyl.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States..

Claims 1,11 are rejected under 35 U.S.C. 102(b) as anticipated by Burkhardt et al (WO 561639; 09/1993).

Burkhardt et al teach cyclic peptide of formula 1 (see claim 1) which have antifungal activity and pharmaceutical compositions thereof. Radical R2 in the referenced compounds (which corresponds to R1 in the claimed compounds) can be substituted benzoyl wherein the benzoyl group may have a variety substituted heterocyclic substituents. For example, see the selection II-G for radical R2 in claim 1 (p. 45, line 30), wherein R6=thienyl or benzothiazolyl. Said compounds anticipate the instantly claimed compounds wherein R1 is aroyl substituted with thienyl or thiazolyl which may have one or more suitable substituents. See instant claim 1, p. 102, lines 16,17 and 24,25.

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On the other hand, said referenced compounds read on aroyl substituted with ar(lower)alkynyl compounds as claimed in instant claim 1, p. 102, lines 22,23.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,11 are rejected under the judicially created doctrine of double patenting over claims 1-5 of U. S. Patent No. 6107458 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: A polypeptide compound of the general formula wherein R1 is benzoyl substituted with isoxazolyl which has phenyl having lower alkoxy.

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Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Prior art made of record

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: EP 486011; EP 644199; WO 96/11210.

Conclusion.

No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MICHAEL BORIN, PH.D.
PATENT EXAMINER

